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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,371	06/30/2003	Jesse Flores	HRT-64858	3143

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,371

Applicant(s)

FLORES, JESSE

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/8/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Specification

The disclosure is objected to because of the following informalities: the "Related Applications" section should be updated to provide the most current status (i.e. US Patent No.) of the related application(s).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai (5,397,304) in view of the teaching of Edwards et al (5,273,535).

Truckai discloses a steerable catheter device that includes a sheath (10) having a lumen and proximal and distal regions, and at least two steering wires (44) extending from a distal region to the proximal region. The steering tendons (i.e. wires) are attached at a point proximate the inner surface of the sheath (see Figure 5) and extend to the proximal end. The steering tendons are angularly displaced by either 90 or 180 degrees (i.e. every 90 degrees) and are axially aligned at the distal attachment points. The Truckai device further includes a distal tip electrode (20) within which the tendons are attached (see Figure 5). The only feature not expressly taught by Truckai is the attachment of one steering tendon being located proximally of the attachment of a

Art Unit: 3739

second steering tendon. Rather, all the steering tendons are attached at the same distance along the length of the device (i.e. to the tip).

Edwards et al disclose an analogous steering catheter assembly that includes first and second steering tendons for controlling the shape of a catheter. In particular, Edwards et al teach that the steering tendons may be attached at various lengths along the catheter in order to provide a desired steering configuration. Figures 8A-8C show one steering tendon (58) attached at a location proximal the location of a second steering tendon (56), while Figures 9A-9C show the tendons attached at the same longitudinal position. Varying the attachment points along the length of the catheter enables a specific curve profile to be attained.

To have provided the Truckai device with steering tendons attached at various locations along the length of the catheter to provide a desired steering profile would have been an obvious modification for one of ordinary skill in the art, particularly since Edwards et al disclose that steering tendons may be attached at various locations for such a purpose.

Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens-Wright et al (5,715,817) in view of the teaching of Edwards et al (5,273,535).

Stevens-Wright et al provide a steerable catheter very much like the Truckai device. In particular, it includes a sheath (22) and first and second steering tendons (42) attached at a distal end of the sheath and extending to the proximal end.

Movement of the tendons causes bending (i.e. steering) of the sheath. The steering

Art Unit: 3739

tendons are axially aligned within the distal tip electrode (28 – see Figure 14). The tendons are angularly displaced 180 degrees (Figures 10-13). Stevens-Wright et al fail to disclose steering tendons attached at different positions along the length of the catheter device.

Edwards et al disclose an analogous steering catheter assembly that includes first and second steering tendons for controlling the shape of a catheter. In particular, Edwards et al teach that the steering tendons may be attached at various lengths along the catheter in order to provide a desired steering configuration. Figures 8A-8C show one steering tendon (58) attached at a location proximal the location of a second steering tendon (56), while Figures 9A-9C show the tendons attached at the same longitudinal position. Varying the attachment points along the length of the catheter enables a specific curve profile to be attained.

To have provided the Stevens-Wright et al device with steering tendons attached at various locations along the length of the catheter to provide a desired steering profile would have been an obvious modification for one of ordinary skill in the art, particularly since Edwards et al disclose that steering tendons may be attached at various locations for such a purpose.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 3739

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,605,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite essentially the same subject matter as the '086 claims with only slight, obvious variations.

Claims 21-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,610,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite essentially the same subject matter as the '058 claims with only slight, obvious variations.

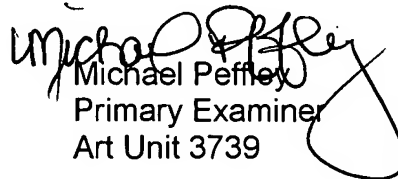
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
January 10, 2005